MINUTES
INSTITUTIONAL BIOSAFETY COMMITTEE
DATE: August 8, 2025

Attendance: Total Attending: 11 **Voting Members Present**: 9

Called to Order: 10:02 a.m.

Name	Expertise	Present
Linda Cassidy, MS	Non-Voting Member	X
Erin Galbally	Non-Voting Member	X
Sue Gotta, MS	rDNA; Select Agents	X
Gerald Grunwald, PhD	rDNA; Biochemistry; Cellular & Developmental Biology	X
Douglas C. Hooper, PhD	rDNA; Immunology; Gene Transfer	X
Botond Igyarto, PhD	Microbiology	
Loretta Kelly, Esq.	Non-affiliate Community Member	X
Kathleen "Kitty" Kono	Non-Affiliate Community Member	X
Phil LaTourette, DVM	Laboratory Animal Sciences	X
Sara Meyer, PhD	Cancer Biology	X
Fabienne Paumet, PhD	Cellular Biology & Biochemistry	X
Zia Rahman, PhD	Microbiology	
Yuri Sykulev, PhD	Microbiology	X

MINUTES REVIEWED:
May 2025 and June 2025 meeting minutes were not presented for review.

NEW PROTOCOLS:

1. Principal Investigator IM
IBC Control # 25-07-966 *A Phase 1, Open-Label Study of FT836, an Off-the-Shelf CAR T-Cell Therapy, With or Without Chemotherapy and/or Monoclonal Antibodies, in Participants With Advanced Solid Tumors*

A motion was made and seconded to provisionally approve this protocol. The motion was unanimously approved.

This protocol was reviewed under NIH Category C. The principal risks identified were:
CAR-T cells
The risks were adequately identified by the Principal Investigator and appropriate mitigation was described in the protocol.

Protocol Summary:
The purpose of this protocol is to evaluate the safety, tolerability, and antitumor activity of FT836 in patients with advanced solid tumors. FT836 is an investigational study drug, made of T-cells. FT836 is produced from cells that came from a healthy human donor which are put through a manufacturing process that turns them into cells called induced pluripotent stem cells (or iPSCs) which are then used to make FT836 T-cells.

Discussion/Clarifications Requested:
- **Protocol Summary:**
  - Is there any screening done of the final product for common or at-risk human infectious diseases?
  - State the route of administration for this drug.

- **Protocol Summary – Lay Description -** Additional information is needed to explain what will be done with the FT836.

2. Principal Investigator ET

IBC Control # 25-07-964 "*ResQ132EX-NMIBC: Expanded Access Use of Recombinant Bacillus Calmette-Guerin in Nonmuscle Invasive Bladder Cancer"*

A motion was made and seconded to provisionally approve this protocol. The motion was unanimously approved.

This protocol was reviewed under NIH Category C. The principal risks identified were:
Recombinant Mycobacterium Bovis Bacillus Calmette Guerin
The risks were adequately identified by the Principal Investigator and appropriate mitigation was described in the protocol.

Protocol Summary:

This study is for non-muscle invasive bladder cancer using recombinant Mycobacterium Bacillus Calmette-Guerin (rMBCG) which is genetically modified version of the standard treatment of Bacillus Calmette-Guerin (BCG). There is a nationwide shortage of BCG.

Discussion/Clarifications Requested:

- **Protocol Summary –** State that the rMBCG will be prepared offsite and delivered to the pharmacy.

3. Principal Investigator MD

IBC Control # 25-07-965 *"An open-label, multi-center, phase I/II study to assess safety, efficacy, and cellular kinetics of YTB323 in participants with treatment-resistant generalized myasthenia gravis"*

A motion was made and seconded to provisionally approve this protocol. The motion was unanimously approved.

This protocol was reviewed under NIH Category C. The principal risks identified were:
CAR-T cells
Retroviral vector
The risks were adequately identified by the Principal Investigator and appropriate mitigation was described in the protocol.

Protocol Summary:

The purpose of this research study is to learn more about the safety of YTB323 and how well it works on disease activity in participants with generalized myasthenia gravis (gMG) who have tried other medications to treat gMG, but they did not work. YTB323 is a CD19-targeted T-cell therapy.

Discussion/Clarifications Requested:

- **Protocol Summary – Lay Description –** Describe how the experiment will be conducted.
- **Biological Agent – Question 4** – Cells are replication competent and should be indicated as such.
- **Recombinant or Synthetic Nucleic Acid Molecules**:
  - **Question 1** – Include that CAR-T are complex, engineered from Human, Mouse (original antibody) and viral sequences.
  - **Question 3b** – Retroviral sequences are what the question asks for and is not answered.
- **Security, Shipping and Safety Pages –** Spell out IP or replace this with YTB323 if appropriate.

4. Principal Investigator MD

IBC Control #25-07-963 *"A Phase 1 Study of ADI-001 Anti-CD20 CAR-engineered Allogeneic Gamma-Delta (γδ) T Cells in Adults with Autoimmune Disease"*

A motion was made and seconded to provisionally approve this protocol. The motion was unanimously approved.

This protocol was reviewed under NIH Category C. The principal risks identified were:
CAR-T cells
Retroviral vector
The risks were adequately identified by the Principal Investigator and appropriate mitigation was described in the protocol.

Protocol Summary:

The purpose of the research is to see if ADI-001 is safe to use and if it improves symptoms in patients affected by B-cell dependent autoimmune diseases. ADI-001 is made from T cells obtained from healthy blood donors. The donor T cells are genetically modified to be able to attack the patient's cells that are thought to be the cause of autoimmune disease. The genetic modification and purification processes of the T cell product are done in a manufacturing lab.

Discussion/Clarifications Requested:

- **Protocol Summary:**
  - Correct the statement "Autoimmune diseases are B-cell dependent", only certain autoimmune diseases are B-cell/antibody dependent.
  - The statement that "This study will only evaluate use in the autoimmune space" is correct, but the "antibody-mediated" autoimmune space is more correct.
  - The summary should also state that the gamma-delta CAR-T cells are allogeneic, prepared from healthy donors, in contrast to the more conventional autologous CAR-T preparations.
- **Protocol Summary – Lay Description -** The comment about the preparation of the T cells in a manufacturing lab and "affecting the recipient patient's genes" is unrealistic. The risk of cell activity from accidental exposure to personnel is more of an issue.
- **Biological Agent - Question 3 –** Should include the CAR-T cells concentration/cell quantity to be administered.
- **Recombinant or Synthetic Nucleic Acid Molecules – Question 3b -** The list provided are the human sequences being expressed, not the viral sequences. Please change the answer to the viral genes being expressed.
- **Security, Shipping and Safety Pages –** Is "IP" referring to ADI-001? Please be consistent in referring to the material throughout the document.

5. Principal Investigator EB
IBC Control#25-08-971 "*Discovery, validation, and translation of acquired and intrinsic resistance to anticancer therapy"*

Note: This protocol was reviewed at our June meeting, 25-04-944.

A motion was made and seconded to provisionally approve this protocol. The motion was unanimously approved.

This protocol was reviewed under NIH Category E and assigned BSL2. The principal risks identified were:
Human lung, sarcoma, and connective tissue cell lines
Organoid models of cancer
Replication incompetent lentivirus
CRISPR-Cas9
The risks were adequately identified by the Principal Investigator and appropriate mitigation was described in the protocol.

Protocol Summary:

The purpose of the study is to learn how cancers become resistant to treatments and ways to overcome that resistance. Cell culture and organoid models of cancer will be used. Traditional therapies will be given to the cells/organoids to study the development of resistance. Then combinatorial drug strategies or genetic manipulations of the cell lines to their tumor suppressor pathways or oncogenes will be done to see if this resistance can be overcome. Lentiviral vectors, CRISPR-Cas9, and small molecular inhibitors will be used to accomplish these genetic manipulations.

Discussion/Clarifications Requested:

- **Protocol Summary:**
  - Expand the technical summary to give more details.
  - Include cell irradiation.
- **Protocol Summary – Lay Description –** Simplify the sentence beginning with "We will utilize lentiviral gene expression technology", this is too technical.
- **Biological Agents:**
  - Protocol summary states "We will also utilize patient samples (blood for ctDNA analysis..." which should be included as a biologic agent and elsewhere as appropriate.
  - **Question 2 –** The volume for 10 6-well plates is approximately 120-180ml.
- **Recombinant or Synthetic Nucleic Acid Molecules:**
  - **Question 3a –** This should be No.
  - **Question 3c –** This should be Yes.
- **Security, Shipping – Question 2b –** Include transport of cells to/from irradiator.

ADMINISTRATIVELY APPROVED ITEMS:
The KSI database indicates the following items have been given administrative approval since our last meeting:

July 11, 2025

Protocol #	PI - Initials	Form type	Comments
24-10-893	MS	Amendment	Clinical Trial - Updated personnel and attached protocol & IB
21-10-445-1	FI	Continuing Review	Active - 3yr review, updated personnel and attached training cert.
24-10-898	PS	Amendment	Clinical Trial - Updated attached protocol & summary of changes
22-01-472-1	LH	Continuing Review	Active - 3yr review, no updates
23-11-770	MR	Amendment	Updated protocol & lay summary with animal use
22-02-484-1	GB	Continuing Review	Active - Update protocol & lay summaries, personnel & safety info
24-05-855	RS	Continuing Review	Active - Clinical Trial-Open to Enrollment- updated personnel
24-05-856	AN	New	Smooth muscle cells and terpenes
22-06-510-1	QL	Continuing Review	Not started - updated personnel only - 3 yr review

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Protocol #	PI - Initials	Form type	Comments
21-03-360-1	AJ	Continuing Review	Added human cells, hazardous chemicals, and plasmid
24-07-874	BE	Continuing Review	Active - no updates
23-01-629	YH	New	Submittal of previously approved paper protocol
21-07-402-1	AM	Continuing Review	Active - no updates
21-07-402-1	AM	Amendment	Added ectromelia virus in vitro and in vivo under Dr. Sigal
21-07-411-1	AS	Continuing Review	Active - no updates
21-03-355-1	RP	Continuing Review	Active - no updates. 3yr renewal.
22-07-520-1	JC	Continuing Review	Active - no updates. 3 yr renewal.
22-07-521-1	JC	Continuing Review	Active - no updates. 3 yr renewal.

21-07-403-1	FP	Continuing Review	Active - no updates
23-12-775	SW	Continuing Review	Active - no updates
22-05-508	UM	Continuing Review	Active - updated personnel, location & training attachments
23-07-708	BE	Continuing Review	Active - no updates
23-11-770	MR	Continuing Review	Active - updated personnel
21-12-462-1	SM	Amendment	Added hazardous chemical
21-09-436-1	AN	Amendment	Added hazardous chemical and tail vein injection of cancer cells
23-05-690	AN	Continuing Review	Not started, no updates
24-10-898	PS	Amendment	Clinical trial, updated attachments & summary of changes
24-08-882	BB	Amendment	Clinical trial, added AZD02040 IP, updated attachments
23-09-726	AH	Amendment	Clinical trial, added imaging to protocol, updated clinical protocol
24-03-824	SW	Continuing Review	Changed PI to Scott Waldman, previously Elena Blanco Suarez
22-08-539-1	CW	Continuing Review	Clinical Trial, closed to enrollment, no drug on site, 3yr review
22-01-473-1	SW	Amendment	Changed PI to Scott Waldman, previously Elena Blanco Suarez
22-08-539	CW	Amendment	Clinical Trial, Updated personnel
22-08-539	CW	Amendment	Clinical Trial, Updated personnel
22-04-494-1	UG	Continuing Review	Active - Clinical Trial, closed to enrollment, 3 yr review
22-12-614	MT	Amendment	Updated lab personnel, clarified text regarding NK cells
21-03-357	CH	Amendment	Added toxins and AAV, updated personnel

OTHER BUSINESS:

1. The committee discussed formatting the meeting minutes.
2. Ms. Gotta updated the committee on the JAH lab moves.
3. The committee discussed obtaining new IBC members.

Meeting Adjourned: 10:55 a.m.

Respectfully submitted for the IBC,

/s/Gerald Grunwald, PhD
Chair, Institutional Biosafety Committee

GG/lc